UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

DIAMEDICA THERAPUTICS, INC., Plaintiff, – against – PHARMACEUTICAL RESEARCH ASSOCIATES GROUP B.V., Defendant.	**No. 17-cv-8875 (WHP)** **FIRST AMENDED COMPLAINT**

Plaintiff DiaMedica Therapeutics, Inc. ("DiaMedica" or "Plaintiff") files this First Amended Complaint for breach of contract and breach of the implied covenant of good faith and fair dealing against Pharmaceutical Research Associates, Group B.V. ("PRA" or "Defendant") and alleges as follows:

THE PARTIES

1. DiaMedica is a corporation organized under the laws of Canada with its principal place of business at 2 Carlson Parkway, Suite 260, Minneapolis, Minnesota 55447.

2. PRA is a corporation organized under the laws of the Netherlands with its principal place of business at Stationsweg 163, 9471 GP Zuidlaren, The Netherlands.

JURISDICTION AND VENUE

3. This is an action for breach of contract and breach of the implied covenant of good faith and fair dealing under New York state law. This Court has jurisdiction because the contract that forms the basis for this action is subject to New York law and the jurisdiction of the courts of New York, New York.

4. Jurisdiction in this district is proper under 28 U.S.C. § 1332(a)(2) because the amount in controversy is greater than $75,000 and because DiaMedica is a citizen of a State and PRA is a citizen of a foreign state.

5. PRA is subject to the personal jurisdiction of this Court because it consented to such jurisdiction in the contract that forms the basis of this action, including in a provision that provides for arbitration in New York, New York, should the parties choose to pursue it.

6. Venue is proper in this district under 28 U.S.C. § 1391(c)(3) and because PRA agreed to resolve disputes regarding the subject matter of this action in New York, New York.

BACKGROUND

7. DiaMedica is a clinical-stage biopharmaceutical company that develops innovative treatments where there is significant unmet clinical need or where no current therapies are available.

8. DiaMedica is currently developing DM-199, a recombinant (synthetic) human protein, for patients suffering from neurological and kidney diseases, including diabetic nephropathy and acute ischemic stroke ("AIS"). There are currently no FDA-approved therapeutic treatments for diabetic nephropathy, and the only FDA-approved treatment for AIS must be administered within three to four hours after a stroke.

9. DM-199 offers a novel approach for the treatment of Chronic Kidney Disease ("CKD"), a widespread health problem that affects more than 30 million Americans. Primary causes of CKD include diabetes (Type 1 and Type 2) and hypertension. More than 40% of all diabetics will develop CKD. Currently, there is no cure for CKD. Even with treatment to manage the disease, approximately 20% of CKD patents will progress to end-stage renal disease.

10. As part of its development efforts, DiaMedica contracts with companies to manage clinical trials on its behalf. DM-199 has undergone multiple clinical trials designed primarily to

establish the safety and tolerability of DM-199 and characterize the pharmacokinetics after subcutaneous and intravenous dosing.

11. PRA is a Dutch corporation that provides services related to the design, management, and implementation of clinical trials. PRA is a subsidiary of PRA Health Sciences, Inc. ("PRA Health Sciences"), a Delaware corporation with a principal place of business in Raleigh, North Carolina.

12. In June 2012, Rick Pauls, DiaMedica's President and CEO, and Dr. Mark Williams, DiaMedica's Vice President of Research, met with Dr. Andre Van Vliet, PRA's Vice President of Medical Affairs, at the American Diabetes Conference in Philadelphia to discuss a proposed clinical study involving DM-199.

13. During the June 2012 meeting between Mr. Pauls, Dr. Williams, and Dr. Van Vliet, Dr. Van Vliet made multiple representations to Mr. Pauls and Dr. Williams regarding PRA's and Van Vliet's purported prior success with clinical trials, including but not limited to his statement to them that the study design with PRA's site in the Netherlands, specifically with respect to the highly predictability clinical performance of patients enrolled in the placebo control group, he (and PRA) would implement for DiaMedica "works like clockwork" to determine whether the drug being tested is active.

14. Also in June 2012, Dr. Van Vliet invited Mr. Pauls and Dr. Williams to PRA's office in the Netherlands to discuss the potential to work together and the potential for PRA to perform the clinical trial on DM-199. Again, Dr. Van Vliet made multiple representations to the DiaMedica representatives, including but not limited to again stating that his PRA clinical study design worked like "clockwork" where fasting blood glucose always remains stable or increases in placebo patients and decreases if tested drug is active. Dr. Van Vliet further provided written

examples for DiaMedica and represented that this study design at PRA had always been successful when used, indicating success with at least 30 such studies in the past. At the time Dr. Van Vliet made the statements referenced herein to Mr. Pauls and Dr. Williams, he knew that many other factors other than an active agent could influence blood-glucose levels, and made such statements to induce DiaMedica to enter an agreement with PRA.

15. On January 18, 2013, in reliance upon the representations Dr. Van Vliet had made to DiaMedica's representatives, DiaMedica (then known as DiaMedica Inc.) signed a Letter of Intent for Clinical Trial and Laboratory Services (the "LOI"), which authorized PRA to begin work on the clinical trial. DiaMedica understood that Dr. Van Vliet would have a lead role in the clinical trial.

16. On or about March 18, 2013, also in reliance upon the representations Dr. Van Vliet had made to DiaMedica's representatives regarding, inter alia, the prior success of the clinical trials. DiaMedica and PRA signed an Agreement for Clinical Trials Management Services (the "Agreement").

17. Pursuant to the Agreement, PRA agreed to manage a DM-199 clinical trial for a study titled, "A Double-Blinded, Placebo-Controlled, Single-Dose and Multiple-Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Proof of Concept of DM-199 in Healthy Subjects and Patients with Type 2 Diabetes Mellitus" (the "Study").

18. The Agreement included detailed "Project Specifications" that identified the objectives, protocols, patient criteria, and other requirements for the Study. Among other requirements, the Agreement specified age and Body Mass Index ("BMI") ranges for various categories of participants, as well as the required dosage of DM-199 for certain participants as a function of their weight.

19. PRA agreed to conduct the Study in accordance with the Project Specifications, Good Laboratory Practices ("GLP"), International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH"), and other applicable regulations of the FDA, the European Medicines Agency ("EMA"), and other regulatory authorities.

20. The Study began in April 2013. PRA conducted the Study at a clinical test facility in the Netherlands owned and operated by PRA. DiaMedica issued a press release announcing the commencement of the Study on May 1, 2013.

21. Dr. Van Vliet was DiaMedica's primary point of contact during the Study. In February and March 2014, Dr. Van Vliet informed DiaMedica in writing that he saw convincing efficacy in certain Study participants and that DM-199, rather than placebo, was responsible for extremely positive results that could only be explained by an active drug.

22. On June 15, 2014, DiaMedica's senior management met with Dr. Van Vliet during the American Diabetes Conference in Chicago. At that meeting, Dr. Van Vliet informed DiaMedica that at least eight Study participants treated with DM-199 lost a clinically significant amount of weight over the course of the Study. Dr. Van Vliet later confirmed this information in writing.

23. On November 5, 2014, based on the expectation that DiaMedica would receive positive Study results by mid-November, DiaMedica announced that it was cancelling a previously announced public offering of up to 24 million shares.

24. On November 14, 2014, PRA sent DiaMedica preliminary results of the Study (the "Results").

25. The Results showed that the Study demonstrated that DM-199 was safe and well tolerated by patients. However, contrary to Dr. Van Vliet's statements to DiaMedica prior, during, and after the trial, the Results did not indicate a clinically significant improvement in glucose control, compared to placebo. The Results also failed to document the significant weight loss reported by numerous Study participants, details of which PRA has and continues to refuse to provide to DiaMedica.

26. On November 17, 2014, DiaMedica issued a press release summarizing the Results. DiaMedica's stock price immediately collapsed, losing more than $35 million in shareholder value.

27. The drastic decline in the price of DiaMedica's stock resulted in prolonged financial difficulty for the company. In late 2014, DiaMedica no longer had sufficient funds to pay PRA amounts owed under the Agreement. PRA responded by stopping additional work and withholding Study documentation and draft reports.

28. In 2016, DiaMedica secured additional capital investment and paid PRA all past-due amounts owed, including interest.

29. DiaMedica has paid PRA all amounts currently owed under the Agreement and any amendments thereto, in a total amount exceeding $2 million.

30. In late 2016, PRA released a draft Clinical Study Report (the "Report") for DiaMedica' s review.

31. After receiving the Report, DiaMedica learned that PRA failed to comply with the Project Specifications set forth in the Agreement and with generally accepted standards for conducting similar clinical trials.

32. For example, PRA mishandled blood samples taken from Study participants. Samples were switched and incorrectly labelled.

33. PRA processed blood samples incorrectly, and did not repeat them.

34. PRA administered incorrect dosing to at least one patient.

35. PRA failed to measure or record Study participants' body weights.

36. PRA included at least two subjects in the Study who did not meet the inclusion criteria specified in the Agreement.

37. PRA insufficiently documented the role of all physicians in the Study, including Dr. Van Vliet.

38. On information and belief, PRA's errors resulted from the negligence or recklessness of PRA and its employees, independent contractors, or agents.

39. On information and belief, PRA's negligence or recklessness compromised the accuracy of the Study results.

40. After receiving the Report, DiaMedica exchanged emails with PRA over the course of several months in an attempt to obtain additional information concerning the Study and to clarify discrepancies between the Report and information provided by Dr. Van Vliet.

41. DiaMedica repeatedly requested additional data, records, and other Study-related documents and information from PRA.

42. On September 5, 2017, DiaMedica sent a letter to David Dockhorn, Executive Vice President and Corporate Compliance Officer for PRA Health Sciences, PRA' s parent company, to formally notify PRA of a dispute between the parties and to request PRA's cooperation in resolving the dispute. In that letter, DiaMedica specifically requested data generated by PRA during the course of the Study and other documentation related to the Study.

43. Pursuant to the Agreement, all data generated by PRA during the course of the Study is DiaMedica's property. PRA agreed to provide all such data to DiaMedica at its request.

44. Pursuant to the Agreement, PRA agreed to allow DiaMedica representatives to inspect Study documentation and any other information necessary for DiaMedica to confirm that PRA performed the Study in conformance with standard operating procedures, the Agreement, and applicable laws and regulations. PRA also agreed to provide copies of any materials reasonably requested by DiaMedica during an inspection.

45. Pursuant to the Agreement, PRA was required to make available all relevant records, programs, and data that DiaMedica may request for purposes related to filing and prosecution of new drug applications or other regulatory submissions.

46. PRA refused to provide Study-related data, records, and documentation requested by DiaMedica.

FIRST CAUSE OF ACTION
(Breach of Contract)

47. DiaMedica re-alleges and incorporates by reference paragraphs 1 through 47 of this Complaint as if fully set forth herein.

48. DiaMedica and PRA entered into the Agreement on or about March 18, 2013.

49. DiaMedica performed all, or substantially all, of its obligations under the Agreement.

50. Under the Agreement, PRA committed to conduct the Study in accordance with the Project Specifications set forth in the Agreement and with generally accepted standards for conducting similar clinical trials, including GLP and ICH standards and all applicable FDA and EMA regulations.

51. PRA also committed to provide or permit inspection of, at DiaMedica's request, all data, records, and documentation generated during or otherwise related to the Study.

52. PRA materially breached the Agreement by failing to conduct the Study in accordance with the Project Specifications set forth in the Agreement and with generally accepted standards for conducting similar clinical trials.

53. PRA also materially breached the Agreement by refusing to provide or permit inspection of Study-related data, records, and documentation requested by DiaMedica.

54. DiaMedica incurred damages as a result of PRA' s breaches, including damages resulting from the negligence or recklessness of PRA and its employees, independent contractors, or agents.

SECOND CAUSE OF ACTION
(Breach of the Implied Covenant of Good Faith and Fair Dealing)

55. DiaMedica re-alleges and incorporates by reference paragraphs 1 through 55 of this Complaint as if fully set forth herein.

56. DiaMedica and PRA entered into the Agreement on or about March 18, 2013.

57. DiaMedica performed all, or substantially all, of its obligations under the Agreement.

58. PRA deliberately and unreasonably acted in a manner to deprive DiaMedica of the Results of the study as promised by Dr. Van Vliet, and withheld benefits to DiaMedica.

59. In February and March 2014, Dr. Van Vliet informed DiaMedica in writing that he saw convincing efficacy in certain Study participants and that DM-199, rather than placebo, was responsible for extremely positive results that could only be explained by an active drug. In June 15, 2014, DiaMedica's senior management met with Dr. Van Vliet during the American Diabetes Conference in Chicago. At that meeting, Dr. Van Vliet informed DiaMedica that at least eight

Study participants lost a clinically significant amount of weight over the course of the Study. Dr. Van Vliet later confirmed this information in writing.

60. Contrary to Dr. Van Vliet's correspondence with DiaMedica, the Results did not indicate a clinically significant improvement in glucose control. The Results also failed to document the significant weight loss reported by numerous Study participants.

61. Despite DiaMedica having paid all amounts due under to Agreement to PRA, PRA refused to provide Study-related data, records, and documentation requested by DiaMedica.

62. DiaMedica incurred damages as a result of PRA' s breaches.

DEMAND FOR RELIEF

WHEREFORE, DiaMedica respectfully requests the following relief:

a) Entry of judgment in DiaMedica's favor on its claims for breach of contract and breach of the implied covenant of good faith and fair dealing;

b) Entry of preliminary and permanent injunctions requiring PRA to comply with the Agreement by immediately providing to DiaMedica all data, documentation, and records generated during or otherwise related to the Study;

c) An award of actual damages resulting from PRA's breach of contract and breach of the implied covenant of good faith and fair dealing;

d) Prejudgment and post-judgment interest;

e) Costs associated with the prosecution of this action; and

f) Such further relief as the Court may deem just and equitable.

DEMAND FOR JURY TRIAL

DiaMedica respectfully requests a trial by jury on all issues triable thereby.

DATED: March 30, 2018

Respectfully submitted,

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